

REMARKS / ARGUMENTS

This Request for Continued Examination ("RCE") is submitted in full response to the outstanding Office Action dated April 24, 2009 wherein claims 2, 4, and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al (U.S. Patent No. 4,817,603). In addition, claims 11 and 12 stand rejected under 35 U.S.C. 103(a), as being unpatentable over Turner in view of Czernecki et al. (U.S. Patent No. 5,356,420).

Applicant first turns to the reference to Turner, and in particular Figures 6A-6D emphasized by the Examiner as illustrative of the operation of Turner. Specifically, as described in the Turner specification, "The rear face of the base plate (disposed towards the shank 90) is heat sealed, ultrasonically welded or otherwise releasably secured to the stop surface 74 in such a manner that the bond will be maintained whilst the spring 16 is being cocked but will be broken once the base of the needle holder 88 engages the backstop 84 (the moment of engagement being shown in FIG. 6B)." (Col. 8 Lns. 29-37). As such, the base 18, which is non-movably connected to the needle assembly 70 does not in any way interlockingly engage a retention member or cocking seat, but

rather is heat welded thereto, and cannot pivot relative to the lancet so as to release the lancet assembly only when desired. Therefore, unlike the claimed invention wherein the engagement member and retention member are interlockingly engaged until affirmatively and pivotally released from that engagement, there is a great risk that as the force from the spring increases during the long path of travel and compression required by the Turner device, the weld could detach and the lancet could fire prematurely. Accordingly, Turner does not disclose or suggest a retention member and engagement member disposed in interlocking removable engagement with one another and releasably connecting the cocking seat and the lancet, or an engagement member that is movably connected to the lancet and includes a single use pivot interconnecting the engagement member to a remainder of the lancet, as recited in Amended claim 9.

Looking now to Czernecki, it discloses a pre-cocked device which is also at risk of being accidentally actuated at any time. Thus, Czernecki does not disclose an engagement member and retention member that move together to achieve cocking of the product when needed. Furthermore, given the nature of pre-cocked devices, it would not have been obvious tone of ordinary skill in the art to look for a specific structure that not only

safely cocks the lancet, but also allows for a controlled release when desired in a safe single use product, as recited in the claimed invention. Thus, even if the prior art disclosed an engagement member and retention member that interlockingly and releasably move with one another to cock the lancet, which neither Turner nor Czernecki disclose, an element such as the wings 11 of Czernecki that do not engage the housing or a cocking seat if the lancet were to be pushed in, and do not have any connection with moving the lancet into a cocked orientation at the moment of use so as to prevent accidental premature firing, would not be looked to or even considered by someone of ordinary skill in the art for combination with a device such as that of Turner. Indeed, it is urged that the field of art related to pre-cocked products and products that are cocked 'on demand' is very different with many different considerations.

Conclusion.

Accordingly, based on the above amendments and remarks reconsideration of this application is hereby requested. It is believed that this application is now in condition for allowance and such action is respectfully requested.

Application No. 10/716,385
Amdt. dated October 26, 2009
Reply to Office Action dated April 24, 2009

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In addition, a request for an appropriate extension of time is enclosed herewith along with the corresponding PTO fee. In the event that any additional fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credits to our **Deposit Account No. 13-1227.**

Respectfully Submitted,

MALLOY & MALLOY, P.A.
Attorneys for Applicant
2800 S.W. 3rd Avenue
Historic Coral Way
Miami, Florida 33129
(305) 858-8000

By:

Peter A. Matos
Reg. No. 37,884

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